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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
PAULS, et al.

Examiner: JOHNSEN, Jason H.

Art Unit: 1623

Application No.: 10/616,141

Filed: 07/08/2003

Title: 1-AROYL-PIPERIDINYL BENZAMIDINES

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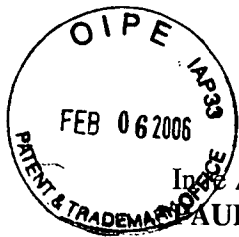
February 3, 2006



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sanofi-aventis Docket No. USA3676 US CNT



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Respectfully submitted,

February 3, 2006


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| Application Number | 10/616,141 |
| Filing Date | 07/08/2003 |
| First Named Inventor | PAULS, et al. |
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| Examiner Name | JOHNSEN, Jason H. |
| Attorney Docket Number | USA3676 - US - CNT |

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| | | | Filing Date | 07/08/2003 | |
| | | | First Named Inventor | PAULS, et al. | |
| | | | Group Art Unit | 1623 | |
| | | | Examiner Name | JOHNSEN, Jason H. | |
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| | | BEIL, W., et al., Phenotypic and Functional Characterization of Mast Cells Derived from Renal Tumor Tissues, Experimental Hematology Vol. 26, 1998, pages 158-169 | |
| | | BISCHOFF, S C., et al., Quantitative Assessment of Intestinal Eosinophils and Mast Cells in Inflammatory Bowel Disease, Histopathology 1996, Vol. 28, pages 1-13 | |
| | | BROERSMA, et al., The Effect Of Thrombin Inhibition In a Rat Arterial Thrombosis Model, Thrombosis Research 64; 405-412, 1991 | |
| | | BUCKLEY, M., et al., Mast Cell Subpopulations in the Synovial Tissue of Patients with Osteoarthritis: Selective Increase in Numbers of Tryptase-positive, Chymase-negative Mast Cells, Journal of Pathology, Vol. 186, 1998, pages 67-74 | |
| | | CAIRNS, et al., Mast Cell Tryptase Stimulates the Synthesis of Type I Collagenin Himan Lung Fibroblasts, J. Clin. Invest., Vol. 99, Number 6, March 1997, pages 1313-1321 | |
| | | CAUGHEY, G., et al., Substance P and Vasoactive Intestinal Peptide Degradation by Mast Cell Tryptase and Chymase, The Journal of Pharmacology and Experimental Therapeutics, (1988) , Vol. 244, No. 1, pages 133-137 | |
| | | FRANCONI, G., et al. et al., Mast Cell Tryptase and Chymase Reverse Airway Smooth Muscle Relaxation Induced by Vasoactive Intestinal Peptide in the Ferret, The Journal of Pharmacology and Experimental Therapeutics, (1989), Vol. 248, No. 3, pages 947-951 | |
| | | HASEBE, et al., Photochemical generation of aliphatic radicals from benzophenone oxime esters: simple synthesis of alkylbenzenes and alkylpyridines, CAS Abstr. 106:119639-1987:119639, Hasebe et al, Tetr. Lett 27/28,3239-42(1986) | |
| | | HIGUCHI, T, et al., Pro-drugs as Novel Drug Delivery Systems, ACS Symposium Series, Vol. 14 | |
| | | HOLST, et al., Antithrombotic Effect of Recombinant Truncated Tissue Factor Pathway Inhibitor (TFPI 1-161) in Experimental Venous Thrombosis- A Comparison with Low Molecular Weight Heparin, Thrombosis and Haemostasis, 71 (2) 214-219 (1994) | |

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| | | IRANI, et al., Human Conjunctival Mast Cells: Distribution of MCT and MCTC in Vernal Conjunctivitis and Giant Papillary Conjunctivitis, Journal of Allergy and Clinical Immunology, Volume 86, Number 1 pages 34-40 | |
| | | JARVIKALLIO, A, et al., Quantitative Analysis of Tryptase- and Chymase-containing Mast Cells in Atopic Dermatitis and Nummular Eczema, British Journal of Dermatology 1997, Vol. 136, pages 871-877 | |
| | | JEZIORSKA, M, et al., Mast Cell Distribution, Activation, and Phenotype in Atherosclerotic Lesions of Human Carotid Arteries, Journal of Pathology, Vol. 182, 1997, pages 115-122 | |
| | | KOMOTO, et a., Preparation of .alpha.-[(N-benzoyl/piperidinyl) phenoxy] isobutyrate and analogs as hypolipemics, CAS Abstr. 122:81127-1995:58673, Komoto et al, CA 2110095/6/1994 | |
| | | KURZ, et al., Rat Model Of Arterial Thrombosis Induced By Ferric Chloride, Thrombosis Research 60; 269-280, 1990 | |
| | | MCEUEN, et al., Guinea Pig Lung Tryptase, Biochemical Pharmacology, Vol. 52, pp. 331-340, 1996 | |
| | | NAUKKARINEN, A, et al., Immunohistochemical Analysis of Sensory Nerves and Neuropeptides, and Their Contacts with Mast Cells in Developing and Mature Psoriatic Lesions, Archives of Dermatological Research Vol. 285, 1993 pages 341-346 | |
| | | ROCHE, E., et al., Bioreversible Carriers in Drug Design Theory and Application, American Pharmaceutical Association and Pergamon Press, 1987 | |
| | | RUOSS, Stephen J, et al., Mast Cell Tryptase is a Mitogen for Cultured Fibroblasts, J. Clin. Invest., Vol. 88, August 1991, pages 493-499 | |
| | | SCHWARTZ, L., et al., The a Form of Human Tryptase Is the Predominant Type Present in Blood at Baseline in Normal Subjects and Is Elevated in Those with Systemic Mastocytosis, The Journal of Clinical Investigation, Vol. 96, December 1995, pages 2702-2710 | |

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| | | SEKIZAWA, K., et al., Mast Cell Tryptase Causes Airway Smooth Muscle Hyperresponsiveness in Dogs, J. Clin. Invest., Vol. 83, January 1989, pages 175-179 | |
| | | STEINHOFF, M., et al., Agonists of Proteinase-activated Receptor 2 Induce Inflammation by a Neurogenic Mechanism, Nature Medicine, Vol. 6, Number 2, February 2000, pages 151-158 | |
| | | TAM, et al., Degradation of Airway Neuropeptides by Human Lung Tryptase, Am. J. Respir. Cell Mol. Biol. Vol. 3, 1990, pages 27-32 | |
| | | TETLOW, L., et al., Distribution, Activation and Tryptase/Chymase Phenotype of Mast Cells in the Rheumatoid Lesion, Annals of the Rheumatic Diseases 1995; Vol. 54, pages 549-555 | |
| | | WILSON, S J., et al., Inflammatory Mediators in Naturally Occurring Rhinitis, Clinical and Experimental Allergy, 1998, Vol. 28, pages 220-227 | |
| | | ZHANG, M., et al., Mast Cell Tryptase and Asthma, Mediators of Inflammation, Vol. 6, 1997, pages 311-317 | |
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